

K070278

APR 16 2007

D.0 Premarket Notification 510(k) Summary

D.1 Submitter Information

Company Name and Address:

PLUS ORTHOPEDICS AG
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CH-6343 Rotkreuz
Switzerland

Contact Name:

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Date Prepared: January 23, 2007

D.2 Name of Device

2.1 Trade Name: POLARCUP® Dual Mobility System

2.2 Common Name: Acetabular Component

2.3 Classification Name and Reference:

Title 21 Code of Federal Regulation (CFR), Part 888.3358, Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis, Product Code: LPH
Title 21, CFR, Part 888.3390, Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis; Product Code: KWY

D.3 Substantial Equivalence Claimed to Predicate Device

Biomet® Tri-Polar Systems, K991990

D.4 Device Description

The POLARCUP® Dual Mobility System consists of two components: a thin press fit shell and a liner component.

4.1 Shell Component

The POLARCUP® shell, is manufactured from stainless steel INOX M30NW according to ISO 5832-9:1992, Implants for Surgery - Metallic Materials - Part 9: Wrought High Nitrogen Stainless Steel, and is available in three configurations:

- Stainless steel, grit-blasted with pure Titanium-coating, 15 to 20% porosity, with pegs and two flanges, uncemented use: allows for implantation with no pegs and no flanges, with no pegs and contoured flanges, screws in flanges but with no pegs, and two impacted pegs and two screws in flanges
- Stainless steel, grit-blasted with pure Titanium-coating, 15 to 20% porosity, without pegs and flanges, uncemented use)
- Stainless steel, mirror polished, without pegs and flanges, cemented use

Note: the pure Titanium coating found in the uncemented versions is a Titanium alloy according to ISO 5832-2:1999, Implants for Surgery - Metallic Materials - Part 2: Unalloyed Titanium.

The POLARCUP® shell is available in 13 sizes for each of the titanium-coated versions for uncemented use, ranging in diameter from 43 mm to 67 mm. The mirror-polished version for cemented use is available in 11 sizes, ranging in diameter from 43 mm to 63 mm.

4.2 Cortical Screws and Impacted Pegs

Cortical screws and impacted pegs, both made of stainless steel INOX 316LVM according to ISO 5832-1:1997, Implants for surgery -- Metallic materials -- Part 9: Wrought Stainless Steel, are available for use with the POLARCUP® shell version with pegs and flanges for uncemented use. The cortical screws are 4.5 mm in diameter and available in 6 different lengths ranging from 40 mm to 60 mm. The impacted pegs are available in a single length of 13 mm.

4.3 Liner Component

The POLARCUP® liner component is a polyethylene insert, specifically Ultra-High Molecular Weight Polyethylene (UHMW PE) according to ISO 5834-2:1998, Implants for Surgery – Ultra-High-Molecular-Weight Polyethylene – Part 2 : Moulded Forms, that retains the femoral head and moves freely in the POLARCUP® shell, allowing increased mobility and stability. The liner component is available in two internal joint diameters, 22 mm and 28 mm. The 22 mm diameter liner is available in 13 different sizes of spherical external radius of curvature whereas the 28 mm diameter liner is available in 11 different sizes of spherical external radius of curvature (to ensure a minimal thickness of 6.5 mm according to EN 12563).

The POLARCUP® Dual Mobility System may be used with the following components provided that they are legally marketed in the US and meet these specifications:

- Ball Heads: made of CoCrMo, ceramic or stainless steel, with diameters of 22 or 28 mm
- Femoral Stems: polished or electro-polished necks

D.5 Intended Use

The POLARCUP® Dual Mobility System is indicated for:

- All forms of osteoarthritis
- Dislocation risks
- Progressive loss of function of the hip joint as a result of a degenerative post-traumatic or inflammatory / rheumatic destruction of the joint
- Femoral head necrosis
- Proximal femoral fractures (especially femoral neck)
- Status following earlier operations such as osteosynthesis, intertrochanteric osteotomies, arthrodesis or failed joint replacement

The POLARCUP® Dual Mobility System is intended for cemented or press-fit application with or without flanges and pegs for general use in skeletally mature individuals undergoing surgery for rehabilitating hip joints.

D.6 Predicate Device Comparison of Indications for Use / Intended Use and Technical Characteristics

The comparison of the POLARCUP® Dual Mobility System was based on a review of the Design Control documentation, relevant aspects of which are included in the company's 510(k) Premarket Notification, and information concerning the predicate device that was obtained from the predicate device manufacturer's web site. The comparison considered technical characteristics and the indications for use / intended use.

D.7 Performance Data

7.1 Performance Standards (Section 514 Compliance): no applicable performance standards have been promulgated under Section 514 of the Food, Drug and Cosmetic Act, for either hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis or hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis.

7.2 The POLARCUP® Dual Mobility System does conform to the following FDA recognized standards:

7.2.1 Sterility

ISO 11137-1:2006, Sterilization of health care products -- Radiation -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices

ISO 11137-2, 2006, Sterilization of health care products -- Radiation -- Part 2: Establishing the sterilization dose

7.2.2 Materials

ISO 5832-9:1992, Implants for Surgery - Metallic Materials - Part 9: Wrought High Nitrogen Stainless Steel

ISO 5832-2:1999, Implants for Surgery - Metallic Materials - Part 2: Unalloyed Titanium

ISO 5832-1:1997, Implants for surgery -- Metallic materials -- Part 9: Wrought Stainless Steel

ISO 5834-2:1998, Implants for Surgery -- Ultra-High-Molecular-Weight Polyethylene -- Part 2 : Moulded Forms

7.3 Performance Testing: Design verification and design validation, e.g., bench testing was performed according to FDA's Design Control Requirements, Title 21 Code of Federal Regulations, Part 820.30.

D.8 Conclusion:

The information and data provided in this 510(k) Premarket Notification establish that the POLARCUP® Dual Mobility System is substantially equivalent to the afore-mentioned predicate device with respect to indications for use/intended use, and technical characteristics.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Plus Orthopedics AG
% Quintiles Consulting
Ms. Pamela J. Weagraff, MBA, RAC
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Norfolk, Massachusetts 02056

APR 16 2007

Re: K070278
Trade/Device Name: POLARCUP® Dual Mobility System
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated
uncemented prosthesis
Regulatory Class: Class II
Product Code: LPH, KKY
Dated: January 23, 2007
Received: January 29, 2007

Dear Ms. Weagraff:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

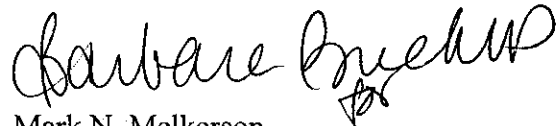
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a stylized flourish at the end.

Mark N. Melkerson

Director

Division of General, Restorative
and Neurological Devices

Office of Device Evaluation

Center for Devices and
Radiological Health

Enclosure

ODE Indications Statement

510(k) Number (if known): *Unknown*

Device Name: POLARCUP® Dual Mobility System

Indications for Use:

The POLARCUP® Dual Mobility System is indicated for:

- All forms of osteoarthritis
- Dislocation risks
- Progressive loss of function of the hip joint as a result of a degenerative post-traumatic or inflammatory / rheumatic destruction of the joint
- Femoral head necrosis
- Proximal femoral fractures (especially femoral neck)
- Status following earlier operations such as osteosynthesis, intertrochanteric osteotomies, arthrodesis or failed joint replacement

The POLARCUP® Dual Mobility System is intended for cemented or press-fit application with or without flanges and pegs for general use in skeletally mature individuals undergoing surgery for rehabilitating hip joints.

Prescription Use: X
(21 CFR 801 Subpart D)

AND/OR

Over-the-Counter Use: _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

Division of General Restorative,
and Neurological Devices

510(k) K070278